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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,866	05/04/2001	Duncan McRee	22700-706	8379

32793 7590 10/26/2004

SYRRX, INC.
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,866

Applicant(s)

MCREE ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 15, 17-20, 27-30, 37, 39, 41, 43, 44, 46, 47 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16, 21-26, 31-36, 38, 40, 42, 45 and 48, 52-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of claims

1. Amendment filed 07/23/2004 is acknowledged. Claims 233,234 are added. Claims 12,37,39,40,52,55,57,58,233,234 are pending. All other claims are canceled.

DETAILED ACTION

Status of Claims

Response to election of species requirement filed 07/08/2004 is acknowledged. Examiner agrees with applicant's arguments that claims 21-25 should be addressed together. Claims 8-12,15,17-20,27-30,37,39,41,43,44,46,47,49-51 are withdrawn from consideration as drawn to non-elected species. Claims 1-7,16,21-26,31-36,38,40,42,45,48,52-57 are under examination.

Information Disclosure Statement

Applicants' Information Disclosure Statement filed 08/19/2002 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7,16,21-26,31-36,38,40,42,45,48,52-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Use of term "biomolecule" in claim 1 (and claims dependent thereupon) is unclear. First, the claim addresses "target biomolecule", then it addresses "different biomolecule structures". It is not clear whether "different biomolecule structures" are different structures of the target molecule, or of different molecules, and, in the latter cases, are these are different biomolecules, or "different structures" of a different biomolecule.

B. Claim 1, last two lines, states that the method identifies compounds that have "superior structural identity". It is not clear how the method arrives at identifying compounds with "superior structural identity" because "structural identity" is usually determined by comparison of structures, not by rotational and translational replacements performed in the course of multiple replacement search.

C. The degree of dissimilarity encompassed by the term "structurally dissimilar" in claim 16 is not clear. Are these structures 100% dissimilar, or they have certain degree of similarity.

Claim Rejections - 35 USC § 103.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,16,21-26,31-36,38,40,42,45,48-57 are rejected under 35 U.S.C. 103(a) as obvious over background Information (pages 3-5) and Podjarny, A. et al.(Transactions of the American Crystallographic Association, 1996, Volume Date 1994, 30, 109-120) or Vitali et al. (Journal of Molecular Biology, 1987, 198(2), 351-5).

The instant claims are drawn to method for identifying a search model to use in molecular replacement for determining a structure of a target biomolecule from crystal data, the method comprising performing multiple molecular replacement searches on crystal data of the target biomolecule, where a group of

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different biomolecule structures are used as search models, and comparing solutions from the multiple molecular replacement searches to identify a compound having superior structural identity with the target biomolecule.

The references in the Background section, such as Rossman et al (p. 3) or references describing EPMR (p. 4) describe molecular-replacement methods which use an existing "search model" to analyze crystal data of the target molecule. The critical part of these methods is the use of the most appropriate "search model" which, after translational and rotational transformations, can yield position and orientation of the target molecule. Therefore, it would be obvious to an artisan that in order to determine position and orientation of the target molecule by molecular replacement method, one must have a search model. To this end, it would be obvious to one skilled in the art at the time the invention was made to be motivated to perform multiple molecular replacement searches to identify a "search model" best suited for molecular-replacement determination of the structure of the target molecule. Obviously, in order to determine the best suited "search model" will require performing multiple replacement searches on more than one (i.e., multiple) potential "search models". Indeed, both Vitali et al. and Podjarny et al. exemplify determination of crystal structure by using multiple search models. Thus, the need to identify the best suited "search model" would bring an artisan to method of identifying as claimed.

In regard to dependent claims , if there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable conditions for multiple replacement determination of crystal structure, such as methods of calculating and selection of candidate biomolecules because such conditions are art recognized result-effective variables which would have been routinely determined and optimized in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,53,55,56,57 are rejected under 35 U.S.C. 102(b) as being anticipated by Podjarny, A. et al.(Transactions of the American Crystallographic Association, 1996, Volume Date 1994, 30, 109-120) or Vitali et al. (Journal of Molecular Biology, 1987, 198(2), 351-5). Both Vitali et al. and Podjarny et al. teach determination of crystal structure by using multiple search models. In the course of determining the crystal structure, the referenced methods include performing multiple molecular replacement searches on crystal data of the target biomolecule,

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where a group of different biomolecule structures are used as search models, and a compound having superior structural identity with the target biomolecule is used in molecular replacement for determining a structure of a target biomolecule from crystal data.

Prior art of record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vagin et al teach method of simultaneous search of multiple copies of a target biomolecule by using a single search model. Chen et al teaches method of determining crystal structure of target biomolecule by combining multiple structures into one search model.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mb
10/12/2004